



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/613,508	07/10/2000	Wei-Wu He	PF140PID1	1213

22195 7590 03/11/2003

HUMAN GENOME SCIENCES INC
9410 KEY WEST AVENUE
ROCKVILLE, MD 20850

EXAMINER

BUGAISKY, GABRIELE E

ART UNIT PAPER NUMBER

1653

DATE MAILED: 03/11/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/613,508

Applicant(s)

HE ET AL.

Examiner

Gabriele E. BUGAISKY

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-68, 70-73, 75-95, 97-100, 102-122, 124-127, 129-149, 151-154, 156-176 and 177-181 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

U.S. Patent and Trademark Office
PTO-326 (Rev. 04-01)

Office Action Summary

Part of Paper No. 17

Continuation of Disposition of Claims: Claims pending in the application are 48-68,70-73,75-95,97-100,102-122,124-127,129-149,151-154 and 156-181.

DETAILED ACTION

The amendment of 11/2002 is acknowledged. Non-elected claims 47, 74, 96, 101, 124, 155 and 182 have been canceled. Claims currently pending and under consideration are 48-68, 70-73, 75-95, 97-100, 102-122, 124-127, 129-149, 151-154, 156-176 and 177-181.

Election/Restrictions

The remarks regarding the restriction requirement are noted. As all non-elected claims have been cancelled, this matter is now moot.

Specification

The objection to the disclosure is withdrawn, as the replacement sequence listing has been entered.

Information Disclosure Statement

References AA and AB remain unconsidered. Applications 09/913293 and 09/913292 list inventors other than Rosen *et al.*, and do not describe biotechnological inventions. The identity of submissions AA and AB is unknown.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

Art Unit: 1653

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 21, 26-41, 43-46, 48, 53-68, 70-73, 75, 80-95, 97-100, 102, 107-122, 124-127, 129, 134-149, 150-154, 156, 161-176, 178-181 under 35 U.S.C. 112, first paragraph, for lack of compliance with the deposit requirements is withdrawn. As statements regarding deposit and access have been submitted.

Claims 21, 30-41, 43-46, 48-68, 70-73, 75-95, 97-100, 102, 111-122, 124-127, 129-149, 151-154, 156-176, and 178-181 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotides encoding human ICE-LAP 3 and 4 of SEQ ID No. 2 and 4, and the ICE-LAP 3 and 4 produced by the human cDNA clones in the deposited cell lines, does not reasonably provide enablement for nucleotides with e.g., 95% identity to the above or for fragments of these polynucleotides that encode portions of the proteins having ICE-Lap 3 or 4 activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. As discussed in the previous Action, the specification is directed toward the sequences encoding the human protein and does not address mammalian homologs. The ICE protease family has become a subject of intense investigation and new members of this family are continually being added (see Henkart). The specification provides no mutants and no guidance as to where the mutations should occur. The specification compares ICE-LAP 3 and 4 with ICE and ced-3 (figure 3), **but does not show what features are unique to identity of a molecular variant as encoding ICE-LAP-3 or 4.** There is no predictability as to which residues may be substituted so that the molecule can be identified as

Art Unit: 1653

encoding either ICE-LAP 3 or 4, i.e., what distinguishes these from other members of the gene family. **How is one to determine whether a given gene with 95% identity is a derivative of either ICE-LAP 3 or 4 or another member of the ICE family?** With respect to the term Ice-Lap 3 or 4 activity, it should be noted that the term “activity” is so broad as to be essentially useless..

With respect to fragments of the genes, the specification provides no guidance regarding which SPECIFIC fragments are useful for any purpose. While one can randomly make fragments, there is no predictability as to how they may be used. Some may be useful for raising specific antisera, but which ones should be chosen? Which are specific ICE_LAP 3 and/or 4 probes? It would thus require experimentation to determine which fragments should be obtained..

Applicant's arguments filed 11/2002, have been fully considered but they are not persuasive. It is stated that the specification teaches how to obtain polynucleotides that have 95% identity Case law is stated. Applicants have not addressed, however, what distinguishes ICE -LAP 3 and 4 activity from other members of the gene family, so that a polynucleotide that has 95% identity with the above can be identified as an ICE-LAP- 3 or 4 variant, and not some other member of the gene family

The rejection of claims 21, 28, 32-41, 43-46, 48, 55, 59-68, 70-73, 75, 82, 86-95, 97-100, 102, 109, 113-122, 124-127, 129, 136, 140-149, 151-154, 156, 163, 167-176 and 177-181 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn, based upon the amendment.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-41, 43-46, 48-68, 70-73, 75-95, 97-100, 102-122, 124-126, 128-149, 151-154, 156-176 and 178-181 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43, 44 and 46 of copending Application No. 08/334251. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite the polynucleotide encodes the peptides of either SEQ ID NO:3 or SEQ ID NO:4 while those of the copending application recite polynucleotides of SEQ ID NO:1 or 3 ; however, SEQ ID NO:1 and 3 encode polypeptides of SEQ ID NO:2 and 4, respectively. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants state they refrain from taking action until at least of the pending applications has allowable claims. Applicants are reminded that all claims of the copending application have been allowed, and that a patent will be issued shortly.

Conclusion

Art Unit: 1653

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

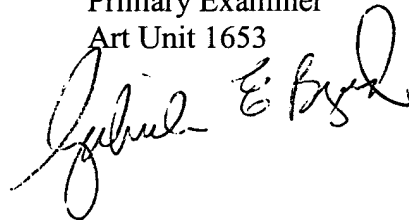
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-4201. The examiner can normally be reached on 8:15 AM- 2 PM, Tu & Th, 8:15 AM-1:30 PM, We & Fr.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.

Gabriele E. BUGAISKY
Primary Examiner
Art Unit 1653



March 10, 2003

**GABRIELLE BUGAISKY
PRIMARY EXAMINER**